IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No. : 10/501,984
Applicant : SCHAUB et al
Filed : July 21, 2004
TC/A.U. : 1611
Examiner : Barbara Frazier

Docket No. : 2923-763
Customer No. : 6449
Confirmation No.: 3383

DECLARATION UNDER 37 CFR §1.132

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Andreas F. Schaub, declare as follows:

1. That I graduated from Medical School University of Zurich in 1992, and received the specialization degree in Gynecology & Obstetrics by the Swiss Society of Gynecology & Obstetrics in 1999.

2. That I am a trained and active specialist in the field of Obstetrics and Gynecology.

3. I am the inventor of and am familiar with the subject matter described and claimed in the United States Patent Application Serial No. 10/501,984, filed on July 21, 2004, entitled "Composition for Easing Human Childbirth". I am familiar with the references cited by the Examiner.

4. I have obtained the formulation disclosed in the Kasahara reference and compared it with the composition for use in the presently claimed method (Dianatal®). An aqueous solution as disclosed in Example 1 of Kasahara, containing 0.61% sodium alginate and 0.22% fucoidin was prepared. As shown in Figure 1 (attached), this solution is a brown colored liquid that is not useful in the presently claimed method because it is not effective in keeping the birth canal surface covered with said lubricant composition so that a lubricant layer is formed between said birth canal surface and said item to be delivered until said item is delivered. Rather, an aqueous solution would not form such a lubricant layer, but instead is expelled by the mother's movement or by the item to be delivered during birth. Further, an aqueous solution is excluded by the present claim, which is limited to applying a composition in the form of a paste, gel, cream, suppository, or foam.

5. That my efforts to use the Kasahara composition in the inventive method failed because, even after attempting to adapt the disclosure in Kasahara for use as a gel, the composition was found to be unacceptable in the claimed method. Specifically, a gel containing 9.15% sodium alginate and 3.3% fucoidin was prepared and a side by side comparison with Dianatal® was performed. As shown in Figure 2 (attached), it is my expert opinion that a gel made according to the composition of Kasahara is too viscous to properly cover or coat the birth canal as is required by the presently claimed method because it congeals and does not easily spread, does not have coating

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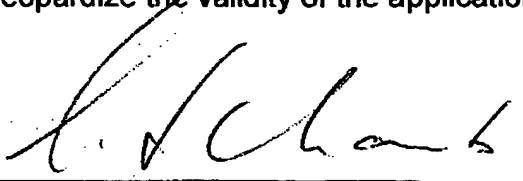
properties, lacks gliding properties as it is too thick, and has a dark brown color that makes it commercially unacceptable for human use.

6. I have attached a picture of the side-by-side comparison of the Dianatal® with the gel adapted from Kasahara(Figure 3). Dianatal® is a clear gel that has suitable gliding, bioadhesive, and coating properties for use in the claimed method. The gel adapted from Kasahara is a dark brown viscous, difficult to apply and non-coating substance that cannot be used in the presently claimed method.

7. The undersigned further declares that all statements made herein of his own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature 

Andreas F. Schaub

Date 7.6.2010

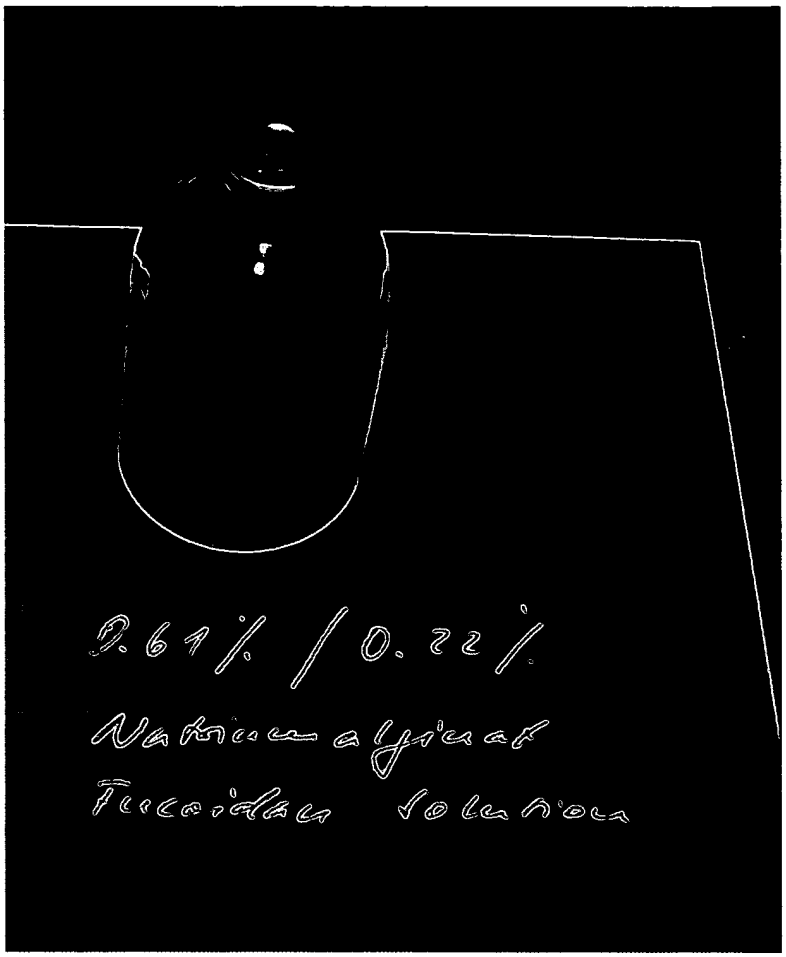


Figure 1: Aqueous solution according to Example 1 of Kasahara.

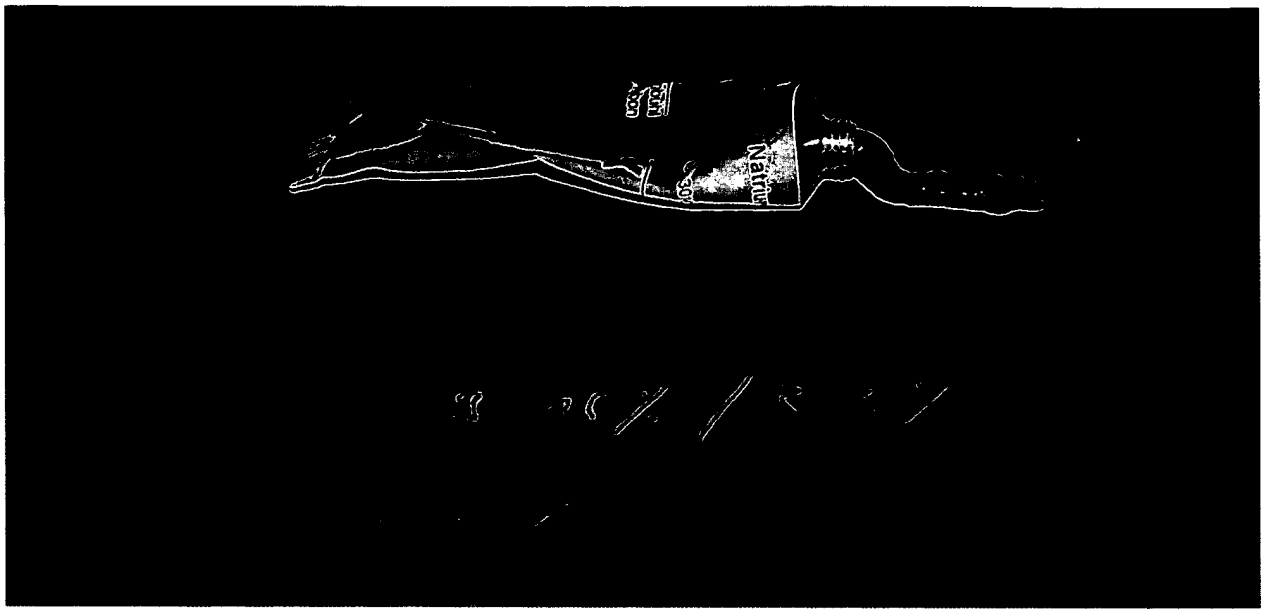


Figure 2: Gel composition adapted from ingredients of Kasahara's solution.

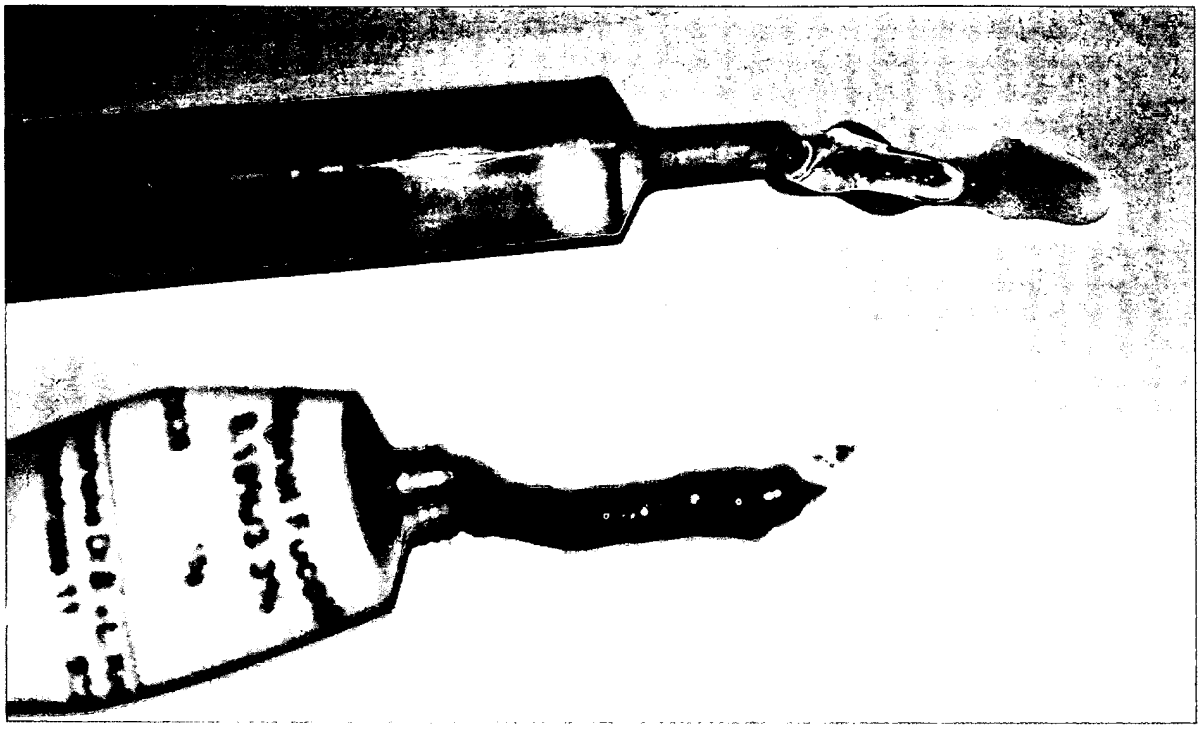


Figure 3: Side by side comparison of Dianatal® (syringe and clear gel) with the gel composition adapted from ingredients of Kasahara's solution (tube and brown gel).